



Final Regulation Agency Background Document

Agency name	Virginia Department of Health
Virginia Administrative Code (VAC) citation	12 VAC 5-90
Regulation title	Disease Reporting and Control
Action title	Update of Regulations and Adoption of New (Emergency) Regulations for Quarantine and Isolation
Date this document prepared	November 6, 2006

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Brief summary

Please provide a brief summary (no more than 2 short paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation. Also, please include a brief description of changes to the regulation from publication of the proposed regulation to the final regulation.

The *Regulations for Disease Reporting and Control* provide information about the process and procedures for reporting diseases to the Virginia Department of Health, including what diseases must be reported, who must report them and how reporting is conducted. The Virginia Department of Health is amending the regulations in order to bring them into compliance with recent changes in the *Code of Virginia* and with recent changes in the field of communicable disease control and emergency preparedness that are needed to protect the health of the citizens of Virginia.

The amendment makes final the emergency regulations addressing isolation and quarantine. In addition, the amendment includes the addition and clarification of several definitions, clarifications on the reportable disease list, updates to the list of conditions reportable by laboratories and the tests used to confirm those conditions, revisions to the information submitted on a disease report, and updates to tuberculosis reporting and control requirements.

Statement of final agency action

Please provide a statement of the final action taken by the agency including (1) the date the action was taken, (2) the name of the agency taking the action, and (3) the title of the regulation.

The State Board of Health approved the final amendment to the *Regulations for Disease Reporting and Control* on February 3, 2006.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter numbers, if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

Chapter 2 of Title 32.1 of the *Code of Virginia*, §§ 32.1-12 and 32.1-35 through 32.1-73, contains mandatory language authorizing the State Board of Health to promulgate the proposed regulations. Specifically, § 32.1-35 directs the Board of Health to promulgate regulations specifying which diseases occurring in the Commonwealth are to be reportable and the method by which they are to be reported. Further, § 32.1-42 of the *Code of Virginia* authorizes the Board of Health to promulgate regulations and orders to prevent a potential emergency caused by a disease dangerous to public health. The Board of Health is empowered to adopt such regulations as are necessary to carry out provisions of laws of the Commonwealth administered by the state health commissioner by § 32.1-12 of the *Code of Virginia*. The Office of the Attorney General has certified that the agency has statutory authority to promulgate the proposed regulation and that it comports with applicable state and/or federal law.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Detail the specific reasons it is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The amendment to the *Regulations for Disease Reporting and Control* replaces emergency regulations for isolation and quarantine with final regulations. Additional changes to the existing disease reporting and control regulations ensure that they comply with current public health practices, medical guidelines and scientific terminology. This will facilitate efforts to recognize, measure and contain emerging diseases in order to protect the health of the people of the Commonwealth.

Substance

Please identify and explain the new substantive provisions, the substantive changes to existing sections, or both where appropriate. A more detailed discussion is required under the "All changes made in this regulatory action" section.

Amendments to current regulations will:

- Finalize the emergency regulations on isolation and quarantine requirements;
- Update language to ensure that it reflects current public health, medical and scientific terminology;
- Update disease reporting requirements, including reportable diseases and those required to report;
- Update language regarding laboratory reporting requirements;
- Update tuberculosis reporting and control requirements and definitions;
- Update provisions regarding the reporting of toxic substance-related illness;
- Update requirements related to HIV testing and reporting, including the reporting of viral load and CD4 test results; and
- Update other disease reporting and control provisions necessary to protect the health of the people of the Commonwealth.

Issues

Please identify the issues associated with the proposed regulatory action, including:

- 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions;*
 - 2) the primary advantages and disadvantages to the agency or the Commonwealth; and*
 - 3) other pertinent matters of interest to the regulated community, government officials, and the public.*
- If there are no disadvantages to the public or the Commonwealth, please indicate.*

The changes improve the ability of the Virginia Department of Health to conduct surveillance and implement disease control for conditions of public health concern, including some that may indicate bioterrorism events. The changes will position the agency to better detect and respond to these illnesses to protect the health of the public.

Except as noted in the paragraphs below, changes are alterations in language and terminology to reflect current scientific use and to provide clarification. For example, the list of diseases reportable by laboratory directors is updated to reflect the currently available tests for these diseases and names of conditions on the Reportable Disease List are modified to comply with scientific usage. These changes in language improve the clarity of the regulations but are not substantive.

Finalization of emergency regulations on isolation and quarantine: These regulations are required by Articles 3.01 and 3.02 of Chapter 2 of Title 32.1 of the *Code of Virginia*. Failure to finalize these emergency regulations would leave the agency and the Commonwealth without the required regulations to support the *Code of Virginia* and would limit our ability to respond effectively in a biological attack or severe disease outbreak in which isolation and/or quarantine may be necessary.

Update to disease reporting requirements: Influenza-associated deaths in children <18 years of age is added to the list of conditions that must be reported. Influenza deaths in children occur, but are unusual and may be indicative of a severe strain circulating in the population. To better monitor trends in severe influenza, VDH has requested voluntary reports of pediatric deaths during the last two years under §32.1-36.E. of the *Code of Virginia*. With this change, reporting of these severe influenza events would be required. Less than five reports are anticipated annually, unless an unusual strain of influenza emerges. Yersiniosis is added to the list of conditions which must be reported. This foodborne disease causes severe illness, especially in infants. Less than 15 reports of yersiniosis are anticipated annually. Typhoid fever, a condition for which public health notification is currently required, is incorporated into the list of conditions requiring rapid communication to enable rapid identification and response. Information on pregnancy status for females and contact information for the physician and facility are needed for follow-up and investigation of reported disease cases. Pregnancy status is currently reportable only for hepatitis

B cases, but the information is needed in other reportable conditions where health department action can help prevent infection in the infant. Pregnancy status will receive the same legal protection as other confidential diagnostic information collected on the disease report. No additional tests or data collection related to pregnancy status are being requested. The agency is requesting only that this information be reported if it is available. Inclusion of physician/facility contact information on the disease report will facilitate follow-up and investigation of reported disease cases. These changes present no disadvantages to the public, the agency, or the Commonwealth.

Update to language regarding laboratory reporting requirements and update of provisions regarding reporting of toxic substance-related illness: Laboratory test names are updated to reflect current laboratory methodologies. Four conditions are added to the list of conditions reportable by laboratory directors. Hantavirus pulmonary syndrome is currently included on the list of reportable conditions and is being added to the list of conditions to be reported by laboratory directors to ensure the reporting of positive laboratory findings. Because hantavirus infection is rare (only two Virginia cases have occurred, in 1993 and 2004) the volume of reports will be low. Toxic substance-related illness is required to be reported by laboratory directors in another section and is being added to this list for clarity. Typhoid fever is currently reportable as a *Salmonella* infection. A change in terminology requires that typhoid fever be listed separately. Yersiniosis is added to support detection of this severe foodborne illness. Less than 15 reports of yersiniosis are anticipated annually. Laboratory reporting of these conditions complements physician reporting and is needed for early detection of and appropriate response to cases. There should be no adverse effect on laboratories as a result of these changes.

Update of the tuberculosis reporting requirements: A revision in the wording of the requirement for reporting of susceptibility results for cultures positive for any member of the *M. tuberculosis* complex makes the regulatory language consistent with the language in the *Code of Virginia*. It improves consistency and clarifies requirements but presents no change in requirements.

Update of requirements related to HIV testing and reporting, including reporting of CD4 and HIV viral load test results: The Centers for Disease Control and Prevention (CDC) support state-mandated reporting of all viral load and CD4 test results for HIV-infected individuals. Adding this requirement will help Virginia compete for federal funds for HIV surveillance, prevention and care. Currently, of the 54 states and territories within the U.S. HIV/AIDS Surveillance system, 26 require both CD4 and viral load reporting. At least 12 additional states are actively working to amend their state reporting regulations to include reporting of these test results. Reporting of all viral load and CD4 tests will improve HIV reporting timeliness and efficiency. In addition, this reporting will allow Virginia to accurately measure care services and ultimately justify federal funding for those Virginians living with HIV infection. Strict confidentiality provisions will continue to be enforced to protect this information when it is received by VDH. This requirement will expand the volume of reports submitted by laboratories to VDH. However, because most laboratories already use computerized systems that generate automated printouts of the required information or submit reports using encrypted data files, the burden of generating additional reports will be minimized.

Changes made since the proposed stage

Please describe all changes made to the text of the proposed regulation since the publication of the proposed stage. For the Registrar’s office, please put an asterisk next to any substantive changes.

Section number	Requirement at proposed stage	What has changed	Rationale for change
12 VAC 5-90-10	Hepatitis C definitions referred to liver enzyme	Hepatitis C definitions refer to liver enzyme levels of 400 IU/L and	Resolution passed by the Council of State and

	levels of seven times the upper limit of normal and mentioned that the antibody screening test had to be verified by other tests.	mention that the other tests may be done separately from the screening test, i.e., the tests are considered positive whenever they are conducted, not only following a screening test.	Territorial Epidemiologists at their 2006 annual conference clarified the technical definition of hepatitis C infection.
12 VAC 5-90-10	None	Added a definition for SARS that clarifies that the syndrome is associated with coronavirus infection	This change is made in response to a comment that was submitted that requested that we change the name of the reportable condition. The agency determined it would be best to add a definition rather than lengthening the name of the condition unnecessarily.
12 VAC 5-90-80 A	Report <i>Escherichia coli</i> O157:H7 and other enterohemorrhagic <i>E. coli</i> infections	Report <i>Escherichia coli</i> infection, Shiga toxin-producing	Updates the language to be consistent with that used by the Centers for Disease Control and Prevention (CDC)
12 VAC 5-90-80 A	Report Influenza deaths in children <18 years of age	Report Influenza-associated deaths in children <18 years of age	This changes makes the name of the reportable condition more accurate technically in that the death must be associated with influenza but not necessarily certified as caused by influenza
12 VAC 5-90-80 B	Language implies that VDH is requesting that clinicians request additional tests for hepatitis C virus infection; stated that additional tests are conducted subsequent to a screening test.	Add the word 'available' to clarify that no additional testing is being requested but rather that available test results shall be reported; allows for the reporting of the results of additional tests that are considered positive tests whenever they are conducted, not only following a screening test.	Clarifies the reporting requirement for hepatitis C virus infection
12 VAC 5-90-80 B	Labs shall report ' <i>Escherichia coli</i> O157:H7 and other enterohemorrhagic (sic) <i>E. coli</i> infections – by isolation of <i>E. coli</i> O157:H7, <i>E. coli</i> O157, or other Shiga toxin-producing <i>E. coli</i> from a clinical specimen'	Labs shall report ' <i>Escherichia coli</i> infection, Shiga toxin-producing – by culture of <i>E. coli</i> O157 or other Shiga toxin-producing <i>E. coli</i> , Shiga toxin detection (e.g., by EIA), or nucleic acid detection'	Brings language in line with that used by CDC and incorporates the latest laboratory testing practices used for this organism
12 VAC 5-90-80 B	Laboratories shall report 'Influenza – by culture, antigen detection, nucleic acid detection, or serologic results consistent with	Laboratories shall report 'Influenza – by culture, antigen detection by direct fluorescent antibody (DFA) or nucleic acid detection'	Limits influenza reporting by laboratories such that they do not have to report all rapid test results to reduce the volume of

	recent infection'		reports needing to be submitted. Also eliminates the reporting of serologic results, which are difficult to interpret.
12 VAC 5-90-80 D	Influenza is specified as a disease that should be reported by number of cases only	This section was deleted	Influenza will be specified as being reportable by number of cases by physicians in 12 VAC 5-90-90 A and by directors of medical care facilities in 12 VAC 5-90-90 C. However, reporting will be by individual cases for laboratories that confirm the diagnosis by using certain laboratory procedures.
12 VAC 5-90-80 E, F, G	12 VAC 5-90-80 E, F, G	12 VAC 5-90-80 D, E, F	Renumbered the sections due to deletion of 12 VAC 5-90-80 D
12 VAC 5-90-90 B	Yersiniosis is not specified in the list of conditions for which isolates shall be forwarded to the Division of Consolidated Laboratory Services (DCLS)	Yersiniosis is added to the list of conditions for which isolates shall be forwarded to the Division of Consolidated Laboratory Services	This will allow public health to determine if persons are ill with the identical strain of <i>Yersinia</i> , thus aiding the detection and investigation of disease outbreaks.
12 VAC 5-90-90 B	Isolates of <i>Mycobacterium tuberculosis</i> complex shall be forwarded to DCLS	Isolates of <i>Mycobacterium tuberculosis</i> complex shall be forwarded to DCLS or other laboratory designated by the Board to receive such specimens.	This brings the language used in the regulations into alignment with that used in the <i>Code of Virginia</i>
12 VAC 5-90-90 D	'Any person in charge of a school, child care center, or summer camp shall report immediately to the local health department the presence or suspected presence in his school or child care center of children who have common symptoms suggesting an epidemic or outbreak situation.'	'Any person in charge of a school, child care center, or summer camp shall report immediately to the local health department the presence or suspected presence in his school, child care center, or summer camp of children who have common symptoms suggesting an epidemic or outbreak situation.'	Corrects the omission of summer camp from the second half of the sentence
12 VAC 5-90-90 D	None	Such persons may notify the local health department of individual cases of communicable diseases that occur in their facilities.	This would facilitate the exchange of information with public health in order to control the spread of disease.
12 VAC 5-90-225 B	<i>Mycobacterium tuberculosis</i> cultures shall be submitted to DCLS	<i>Mycobacterium tuberculosis</i> cultures shall be submitted to DCLS or other laboratory designated by the Board to receive such	Brings regulatory language into alignment with that used in the <i>Code of Virginia</i>

	specimen.	
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Public comment

Please summarize all comments received during the public comment period following the publication of the proposed stage, and provide the agency response. If no comment was received, please so indicate.

Commenter	Comment	Agency Response
Children’s Health and Safety Consultant, Virginia Department of Social Services	Child care providers may not be able to distinguish between normal occurrence of disease, which would not require reporting, and an epidemic or outbreak situation, which would require reporting of a cluster of common symptoms, in compliance with 12 VAC 5-90-90 D. This may lead to underreporting.	This comment relates to existing language that is not affected by the proposed amendment. VDH accepts the potential for underreporting by child care centers and expects them to report only if they observe an increase level of illness that is of concern to them. No change is necessitated by this comment.
Hospital Laboratory Manager, Virginia	There seems to be a conflict between 12 VAC 5-90-90 B, which requires reporting of information on each influenza case, and 12 VAC 5-90-90 C, which requires reporting of only the total number of influenza cases. What about influenza deaths in children < 18? Should the information be in one place together?	There is a discrepancy, and it is intentional. VDH requires laboratories that confirm influenza by certain laboratory procedures to report each individual case but physicians and directors of medical care facilities can report a weekly count of the number of influenza cases diagnosed. We deleted the section (12 VAC 5-90-80 D) that stated that influenza was reportable by number of cases only since that is not true for laboratory directors. Influenza-associated deaths in children is considered to be a different reportable condition and thus the reporting by count provision does not apply.
Infection Control Practitioner (ICP), health maintenance organization serving Virginia	<ol style="list-style-type: none"> 1. In 12 VAC 5-90-10, definition of “Tuberculosis active disease” part ii should not be limited to physicians licensed to practice medicine in Virginia. 2. Add term “least restrictive” language under both isolation and quarantine and add examples. 	<ol style="list-style-type: none"> 1. This definition is consistent with language used in the <i>Code of Virginia</i> and thus will not be changed. VDH believes that, even if a case of TB is diagnosed by a physician outside of Virginia, the diagnosis will ultimately be verified by a Virginia physician after the

		<p>report is received by a Virginia health department.</p> <ol style="list-style-type: none"> Least restrictive is defined in 12 VAC 5-90-10. Further guidance will be provided in other documents rather than in regulation. No change is necessary.
Veterans Administration Medical Center	<ol style="list-style-type: none"> In 12 VAC 5-90-280, add introductory paragraph explaining to whom special agents reporting requirements apply. In 12 VAC 5-90-80 B, do not require that additional tests for hepatitis C patients be conducted. 	<ol style="list-style-type: none"> The proposed regulation as printed in the <i>Virginia Register</i> included only those sections of the regulations in which changes were proposed. The select agent reporting requirement is clearer if all relevant paragraphs are viewed. No change is necessary. Clarification has been added to the requirement for laboratory reporting of hepatitis C findings to indicate that findings are required to be reported only if the tests were conducted.
Foodborne Disease Epidemiologist, Virginia Department of Health (VDH)	<ol style="list-style-type: none"> Require laboratory reporting of Shiga toxin positive EIA test results for enterohemorrhagic <i>E. coli</i> infection. Require submission of isolates to DCLS by laboratories identifying evidence of yersiniosis. 	<ol style="list-style-type: none"> 12 VAC 5-90-80 B was modified to require the reporting of Shiga toxin positive laboratory results. In fact, as a result of this comment, VDH learned that the name of the reportable disease needed to be revised to reflect the latest recommendations from CDC. This change is shown in 12 VAC 5-90-80 A and 12 VAC 5-90-80 B. Yersiniosis was added to the list of conditions for which isolates must be submitted to DCLS in 12 VAC 5-90-90 B.
Hospital Infection Control Practitioner, Norfolk	<ol style="list-style-type: none"> Requirement for reporting notifiable conditions within 3 days has made reporting more of a burden. An electronic method is needed. Only require reporting within 24 hours for pertussis when pertussis is confirmed or when there is a known exposure to a pertussis case. Otherwise allow pertussis reporting within 3 days. 	<ol style="list-style-type: none"> This comment pertains to existing language that was not being amended. When the change was made, most hospital disease reporters said they were routinely reporting within 3 days. An electronic means of reporting is under development.

		<p>2. The health department needs to be informed of pertussis as soon as the diagnosis is suspected in order to intervene to prevent the spread of disease.</p>
<p>Surveillance Coordinator, VDH</p>	<ol style="list-style-type: none"> 1. Change the following in 12 VAC 5-90-80 A to be consistent with nationally used nomenclature: <ul style="list-style-type: none"> • “<i>Haemophilus influenzae</i> infection, invasive” to “<i>Haemophilus influenzae</i> disease, invasive” • “Hemolytic uremic syndrome (HUS)” to “Hemolytic uremic syndrome (HUS), post-diarrheal” • “Severe Acute Respiratory Syndrome (SARS)” to “Severe Acute Respiratory Syndrome (SARS)-associated Coronavirus (SARS-CoV) disease” • “<i>Streptococcus pneumoniae</i> infection, invasive <5 years of age” to “<i>Streptococcus pneumoniae</i> disease, invasive <5 years of age” 2. In 12 VAC 5-90-80 B include histopathologic diagnosis of diphtheria. 3. 12 VAC 5-90-80 B requires laboratory reporting of “serologic results consistent with recent infection” for a number of conditions. Inconsistencies between laboratories in determining what findings are reportable may result in inappropriate public health interpretation and action. 4. In 12 VAC 5-90-90 D, summer camps are left out of the narrative. 	<ol style="list-style-type: none"> 1. These suggestions would affect 12 VAC 5-90-80, paragraphs A, B, and C. VDH recently added the word ‘infection’ after each organism name on the reportable disease list to ensure internal consistency. We will retain the use of ‘infection’. On HUS, we would like all cases to be reported and public health investigation to determine if the syndrome followed a bout of diarrhea. On SARS, we have added a definition to 12 VAC 5-90-10 rather than lengthening the name of the reportable condition. 2. The suggested change will be incorporated because that test is included in the CDC’s case definition for diphtheria. 3. VDH will provide guidance to district staff to assist with test result interpretation. No regulatory change is needed to address this comment. 4. Summer camps have been added to the paragraph.
<p>Senior Epidemiologist, VDH</p>	<ol style="list-style-type: none"> 1. To reduce the reporting burden while ensuring collection of important information, laboratories should submit weekly counts of positive rapid tests for influenza, not report each case. Counts could be submitted by age group if this information was needed. 2. Modify the text of 12 VAC 5-90-90 D to include summer camps, which are referenced in the title of the section. 3. Virginia law (§32.1-37 – Reports by persons other than physicians) allows for reports of individual diseases by 	<ol style="list-style-type: none"> 1. 12 VAC 5-90-80 B was changed to restrict the number of laboratory results that must be reported for influenza. Reporting of rapid test results is not required. 2. Suggested change has been incorporated. 3. Suggested change has been incorporated into 12 VAC 5-90-90 D.

	<p>persons in charge of any medical care facility, school or summer camp. The regulations should acknowledge this by allowing these individuals to report if they are informed of a notifiable condition. This would not require them to report but would facilitate the exchange of information with the public health department. This allowance could be noted in 12 VAC 5-90-90 D.</p>	
<p>Public Health Laboratorian, Fairfax County Health Department</p>	<ol style="list-style-type: none"> 1. Modify 12 VAC 5-90-90 B and 12 VAC 5-90-225 B, 4 and 5, to allow submission of isolates to DCLS “or another laboratory designated by the Board to receive such specimen” to be consistent with § 32.1-50 E of the <i>Code of Virginia</i>. This would allow Fairfax County Health Department Laboratory to continue to serve in this capacity. Allowing this testing to be performed at Fairfax County Public Health Laboratory will avoid duplication of effort, additional costs, and health risks associated with additional handling of specimens. 2. 12 VAC 5-90-225 B, 4 and 5 requires the submission of TB isolates and offers the option of sending a written report. These instructions are confusing and inconsistent with the requirements for submission of isolates in 12 VAC 5-90-90 B. 	<ol style="list-style-type: none"> 1. These modifications have been made to ensure consistency with the language of the Code. 2. This is consistent with the current requirements of the <i>Code of Virginia</i>.

Enter any other statement here

All changes made in this regulatory action

Please detail all changes that are being proposed and the consequences of the proposed changes. Detail new provisions and/or all changes to existing sections.

Current section number	Proposed new section number, if applicable	Current requirement	Proposed change and rationale
12 VAC 5-90-10		Definitions	<ul style="list-style-type: none"> • Replace existing language with changes to definitions made by emergency regulation on November 5, 2004. • Affected Area – Change since filing of emergency regulation to move phrase

			<p>within the sentence and modify punctuation to clarify wording.</p> <ul style="list-style-type: none"> • Decontamination – Change since filing of emergency regulation to re-order “surface, item or person” to read “person, surface, or item”. • Hepatitis C – Reword to reflect current testing methodology. • Infection – Change since filing of emergency regulation to read: “Infection” means the entry and multiplication or persistence of a disease-causing organism (prion, virus, bacteria, fungus, parasite, or ectoparasite) in the body of an individual. An infection may be inapparent (i.e., without recognizable signs or symptoms but identifiable by laboratory means) or manifest (clinically apparent). • Nucleic acid detection – Add a definition to clarify use of this term in diseases reportable by directors of laboratories. • Occupational outbreak – Add pneumoconiosis as a disease indicative of an occupational health problem. • Susceptible individual – Change since filing of emergency regulation to modify “immunization exposure, or medications” to “immunization history, or use of medications.” • Tuberculosis – Re-order definitions to alphabetize. Reword definition of tuberculin skin test to be consistent with current medical guidelines. • Vaccinia, disease or adverse event – Add phrase to ensure that vaccinia infection is included. • Vancomycin-resistant <i>Staphylococcus aureus</i> – Delete defined term. Clarifications in the Reportable Disease List make this definition unnecessary.
12 VAC 5-90-40		Administration	<ul style="list-style-type: none"> • Replace existing language with changes made by emergency regulation on November 5, 2004. • Change since filing of emergency regulation to insert the word “has” in paragraph B to improve clarity. The phrase will read “...and has the authority to issue orders of isolation...”
12 VAC 5-90-80 (A)		Reportable disease list	<ul style="list-style-type: none"> • Change disease names to comply with scientific usage and ensure internal consistency. • Add influenza-associated deaths in children <18 years of age as a

			<p>reportable condition and as a condition for which rapid communication of a suspected or confirmed case is required.</p> <ul style="list-style-type: none"> • Add typhoid fever to the list of conditions for which rapid communication of a suspected or confirmed case is required. • Add yersiniosis as a reportable condition.
12 VAC 5-90-80 (B)		Diseases reportable by directors of laboratories	<ul style="list-style-type: none"> • Add statement to clarify that an asterisk indicates a condition requiring rapid communication. • Update test names to reflect current methodology and terminology. • Add hantavirus pulmonary syndrome, typhoid fever and yersiniosis to the diseases reportable by laboratory directors. • Include toxic substance-related illness and typhoid fever in the list of diseases reportable by directors of laboratories to clarify the reporting of these conditions. • Add CD4 and HIV viral load tests as findings to be reported for persons infected with HIV.
12 VAC 5-90-80 (C)		Reportable diseases requiring rapid communication	<ul style="list-style-type: none"> • Add influenza-associated deaths in children <18 years of age as reportable condition and as condition for which rapid communication of a suspected or confirmed case is required. • Add typhoid fever to the list of conditions for which rapid communication of a suspected or confirmed case is required.
12 VAC 5-90-80 (E)		Human immunodeficiency virus (HIV) infection	<ul style="list-style-type: none"> • Delete sub-section. The information is effectively captured in subsections A and B.
12 VAC 5-90-80 (F)	12 VAC 5-90-80 (E)	Toxic substances-related disease	<ul style="list-style-type: none"> • Renumber to reflect deletion of sub-section on HIV infection.
12 VAC 5-90-80 (G)	12 VAC 5-90-80 (F)	Outbreaks	<ul style="list-style-type: none"> • Renumber to reflect deletion of sub-section on HIV infection.
12 VAC 5-90-80 (H)	12 VAC 5-90-80 (G)	Unusual or ill-defined diseases or emerging pathogens	<ul style="list-style-type: none"> • Renumber to reflect deletion of sub-section on HIV infection.
12 VAC 5-90-90		Those Required to Report	<ul style="list-style-type: none"> • Replace existing language with changes made by emergency regulation on November 5, 2004. • Add pregnancy status for females and contact information for physicians/facilities as information to be reported. • Clarify that when a facility director submits disease notifications for laboratories, the laboratories are still responsible for submission of required isolates.

<p>12 VAC 5-90-100</p>		<p>Methods</p>	<ul style="list-style-type: none"> • Replace existing language with changes made by emergency regulation on November 5, 2004. • Change since filing of emergency regulation to clarify wording in first sentence of fifth paragraph regarding the decision to implement modified isolation. • Change since filing of emergency regulation to replace “any individual(s)” with “any individual or individuals” in second sentence of fifth paragraph. • Change since filing of emergency regulation to move last sentence of sixth paragraph to create a seventh paragraph discussing use of articles 3.01 for disease control and 3.02 for isolation and quarantine. Insertion of “of the <i>Code of Virginia</i>” following reference to Article 3.01. • Change since filing of emergency regulation to insert references to sections within the Code of Virginia to accompany citations of articles.
<p>12 VAC 5-90-105 in emergency regulations</p>	<p>12 VAC 5-90-103</p>	<p>Isolation for Communicable Disease of Public Health Threat</p>	<ul style="list-style-type: none"> • Implement additions made by emergency regulation on November 5, 2004. • Correct numbering of section to 12 VAC 5-90-103. Section was incorrectly numbered 12 VAC 5-90-105 in emergency regulations. • Change since filing of emergency regulation to ensure consistent capitalization in subsection titles. • Change since filing of emergency regulation to replace “the individual(s) and or affected area” with “the individual, individuals, and/or affected area” in the first sentence of subsection B. • Change since filing of emergency regulation to replace “others” with “other individuals” in the second sentence of subsection C. • Change since filing of emergency regulation to replace “individual or individuals affected” with “affected individual or individuals” in first sentence of subsection D. • Change since filing of emergency regulation to replace “would” with “shall” in second sentence of subsection D. • Change since filing of emergency regulation to insert new subsection H (Appeals) to address appeal of isolation orders.

			<ul style="list-style-type: none"> • Change since filing of emergency regulation to renumber old subsection H (Release from Isolation) as subsection I. • Change since filing of emergency regulation to renumber old subsection I (Affected Area) as subsection J and to clarify wording in last sentence of subsection J to ensure consistency in the designation of the affected area.
12 VAC 5-90-110 in emergency regulations	12 VAC 5-90-107	Quarantine	<ul style="list-style-type: none"> • Implement additions made by emergency regulation on November 5, 2004. • Correct numbering of section to 12 VAC 5-90-107. Section was incorrectly numbered 12 VAC 5-90-110 in emergency regulations. • Change since filing of emergency regulation to ensure consistent capitalization in subsection titles. • Change since filing of emergency regulation to replace “the individual(s) and or affected area” with “the individual, individuals, and/or affected area” in the first sentence of subsection B. • Change since filing of emergency regulation to clarify wording regarding place of quarantine in second paragraph of subsection C. • Change since filing of emergency regulation to replace “individual or individuals affected” with “affected individual or individuals” in first sentence of subsection D. • Change since filing of emergency regulation to replace “would” with “shall” in second sentence of subsection D. • Change since filing of emergency regulation to insert new subsection H (Appeals) to address appeals of quarantine orders. • Change since filing of emergency regulation to renumber old subsection H (Release from Quarantine) as subsection I. • Change since filing of emergency regulation to renumber old subsection I (Affected Area) as subsection J and to clarify wording in last sentence of this subsection to ensure consistency in the designation of the affected area.
12 VAC 5-90-110 (12 VAC-90-120 in emergency	12 VAC-90-110	Dosage and Age Requirements for Immunizations: Obtaining Immunizations	<ul style="list-style-type: none"> • Correct numbering of section to 12 VAC 5-90-110. Section was incorrectly numbered 12 VAC 5-90-120 in emergency regulation.

regulations)			<ul style="list-style-type: none"> • Change wording of vaccine requirements for consistency and clarity, using the phrase “attenuated (live virus)” where appropriate. • Clarify wording of age and school entry requirements for hepatitis B vaccination.
12 VAC 5-90-130		Prenatal Testing	<ul style="list-style-type: none"> • Insert wording on HIV prenatal testing for consistency with <i>Code of Virginia</i> § 54.1-2403.01.
12 VAC 5-90-225		Additional Data to be Reported Related to Persons with Active Tuberculosis Disease (Confirmed or Suspected)	<ul style="list-style-type: none"> • Modify the requirement for laboratory reporting of drug susceptibility testing to be consistent with current requirements in the <i>Code of Virginia</i>. • Require reporting of health care provider’s telephone number to facilitate follow-up. • Clarify the organisms for which cultures must be submitted.
12 VAC 5-90-230		Definitions	<ul style="list-style-type: none"> • Re-order definitions to alphabetize.
12 VAC 5-90-280		Definitions	<ul style="list-style-type: none"> • Clarify the reference for the definition of “select agent or toxin”. • Move definitions to place in alphabetical order.

Enter any other statement here

Regulatory flexibility analysis

Please describe the agency’s analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

In order for public health actions to be taken to prevent and control the spread of communicable diseases, the Virginia Department of Health must require the reporting of diseases of public health importance to local health departments. Regulations are the only means of accomplishing this.

Family impact

Please assess the impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one’s spouse, and

one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

These regulations should make families healthier by requiring prompt reporting of diseases of public health importance, thus facilitating health department action to contain the spread of disease.